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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/372,036	08/11/99	SCHUBERT	P MERCK1694D2

HM12/1205
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EXAMINER

BASKAR, P

ART UNIT	PAPER NUMBER
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1645

4

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/372,036

Applicant(s)

SCHUBERT PETER ET AL

Examiner

Padma Baskar

Group Art Unit
1645



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 3-10 and 15-38 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 3-10 and 15-38 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Election/Restriction

1. Applicants preliminary amendment filed on 9/15/99 is entered. Claims 1-2 and 11-14 have been canceled. Claims 8-10 and 15-19 have been amended. New claims 24-38 have been added. Claims 3-10 and 15-38 are pending in the application.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-6, drawn to an isolated polypeptide, classified in class 530, subclass 350.

II. Claim 7, drawn to a method of preparing an immunogenic conjugate (polypeptide) classified in class 435 subclass 69.1

III. Claims 8-10 and 24-28, drawn to a process of preparing an antibody. classified in class 435 subclass 70.21

IV. Claims 15-19 and 29-38 drawn to an isolated antibody, classified in class 530, subclass 387.1

V. Claims 20-21, drawn to a method for detecting bacteria of the genus *Listeria* in a sample comprising binding a p60 protein with an antibody, classified in class 435, subclass 7.1.

VI. Claims 22 and 23 drawn to a kit for detecting *Listeria monocytogenes* by immunoassay, classified in class 435, subclass 975.

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3. Inventions I, IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products. The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV, VI are patentably distinct products which are different structurally, functionally and biochemically. Invention I drawn to an isolated polypeptide, Invention IV drawn to an antibody, Inventions VI and VII drawn to patentably distinct kits which identify different bacteria. Thus all these inventions are distinct and different because the polypeptide of invention I is made of amino acids whereas Invention IV drawn to an antibody and is distinct from Inventions I and VI since it has an inherent affinity, avidity, and specificity.

4. Inventions II, III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods. The inventions are distinct, each from the other because of the following reasons:

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Invention II is a method of preparing an immunogenic conjugate which uses polypeptide and conjugate such as glucose dehydrogenase whereas invention III is a process of making polyclonal and monoclonal antibodies by immunizing rabbits or by hybridoma technology which uses mice, immunogen etc. Invention V is a method for detecting bacteria of the genus *Listeria* in a sample by detecting specifically bound antibody which uses antibodies, enzymes etc. Thus inventions II, III, and V are patentably distinct methods which require different reagents, steps and result in a different outcome.

5. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make materially different Malarial polypeptide conjugate .
6. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other materially different Malarial monoclonal antibodies.

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7. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as immunochromatography for purifying polyclonal antibodies.
8. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make materially different polypeptide conjugate such as Malarial polypeptide conjugate.
9. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other materially different Malarial monoclonal antibodies.

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10. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as immuno^oaffinity chromatography for purifying polyclonal antibodies.
11. Inventions II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case ~~that~~ the process as claimed can be used to make materially different polypeptide conjugate such as Malarial polypeptide conjugate.
12. Inventions III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case ~~that~~ the process as claimed can be used to make other materially different Malarial monoclonal antibodies.

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13. Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (kit contains different reagents such as antibodies and antigens) as claimed can be used in a materially different process such as immuno^oaffinity chromatography.
14. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.
15. A telephone call was made to Richard Lebovitz on 4/19/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

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one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Padma Baskar Ph.D.

11/30/00


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600